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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,462	03/03/2006	Yves Mayeresse	VB60410	1403

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EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
09/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No.	Applicant(s)	
	10/533,462	MAYERESSE, YVES	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Response to Notice of Non-Compliant Amendment, received 22 May 2009, is acknowledged. Claims 1 and 14 have been amended. New claim 41 has been amended.

2. Claims 1-41 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claim 14 under 35 U.S.C. 112, first paragraph, scope of enablement for any/all concentrations of stabilizing agent less than 3.5% weight/volume, is withdrawn in light of the amendment of the claim.

Rejections Maintained

4. The rejection of claims 1-13 and 15-40 under 35 U.S.C. 112, first paragraph, scope of enablement for any/all concentrations of stabilizing agent less than 3.5% weight/volume, is maintained.

Applicant argues that the specification clearly indicates that lower concentrations are also suitable (page 7, lines 20-26) and that a 1% solution of stabilizing agent is disclosed in the specification to be a sufficient concentration at the beginning of the evaporation process to protect the active agent during drying and subsequence storage.

The examiner has considered applicant's arguments in light of the amendment of the claims, but does not find it persuasive. The recitation on page 7, lines 20-21 that the concentration of the stabilizing agent used in the process of the invention may be between 1% and 50% is not confirmed by the examples on pages 28-35.

Example 1 utilized sucrose concentrations of 1%, 5%, 10% and 20% to determine freezing conditions. No activity was measured.

Example 2 utilized sucrose concentrations of 5%, 10%, 15% and 25% to determine freezing without foaming. No activity of the active agent was measured.

Example 3 utilized either 10% sucrose or 10% trehalose as stabilizing agent. As seen in Table 2, 0% of antigen retention (shown by antibody detection) using either no sugar or 2.5% sucrose. Table 3 shows retention of antigen using only 3.15% sucrose and 10% trehalose.

Example 4 utilized the method described in Example 3 to determine long term storage on antigen retention.

Example 5 utilized sucrose concentration of 10% for comparison of immunogenicity *in vivo* in rats.

Example 6 utilized sucrose concentration of 10% or trehalose concentration of 10% for comparison of immunogenicity *in vivo* in rats.

Table 2 indicates that utilizing 0% up to 2.5% sucrose resulted in no antigen retention, and Table 3 indicates that 3.15% sucrose results in only 46-58% antigen retention. Thus, the claimed range of 1%-50% with retention of at least 40% is not supported by the data. The lowest limit which shows such retention is 3.15%, while the lower concentrations of 2.5% or no sugar show no antigen retention.

Therefore, the rejection of the instant claims is maintained.`

5. The provisional rejection of claims 23-33, 36-39 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6, 14, 15-18, and 20 of copending Application No. 10/533,464, is maintained.

Applicant requests that the double-patenting rejection be held in abeyance until all other substantive issues of patentability in this application have been resolved.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Newly added claim 41 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for preserving an agent and compositions comprising said agent, which retain $\geq$40% of the antigenicity, activity, immunogenicity, or combination thereof of said agent wherein the stabilizing agent is 3.5-25% weight/volume, does not reasonably provide enablement for any/all concentrations of stabilizing agent less than 3.5% weight/volume. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – Claim 41 is drawn to a method of preserving an agent utilizing the concentration of 2%-25% (w/vol).

The state of the prior art, as evidenced by the discussion in the instant specification indicates that preserving an agent's activity ≥40% without bubbling or freezing was unknown at the time of filing (U.S. Pat. No. 6,306,345; U.S. Pat. No. 5,766,520).

The predictability or lack thereof in the art - there is a lack of predictability in the art for the types/concentrations of stabilizing agents which would maintain the required ≥40% activity of the agent.

The amount of direction or guidance present in the instant specification is insufficient for the broad scope of the instant claims. The specification examples utilized stabilizing concentration of 3.15% to 10% weight/volume. Concentrations of 0% and 2.5% did not result in antigen retention.

The quantity of experimentation necessary utilizing ≤3.15% determined by other than weight/volume constitutes merely an invitation to experiment without a reasonable expectation of success.

7. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim depends from a rejected claim.

Conclusion

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of

the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

September 9, 2009